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November 23, 2020

VIA ECF

Honorable Robert Kugler, U.S.D.J.
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 4D
4th and Cooper Streets
Camden, NJ 08101

Honorable Joel Schneider, U.S.M.J.
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 3C
4th and Cooper Streets
Camden, NJ 08101

Re: IN RE: VALSARTAN, LOSARTAN, & IRBESARTAN PRODUCTS LIABILITY LITIGATION
Civil No. 19-2875 (RBK/JS)

Dear Judge Kugler and Judge Schneider:

Please accept this letter on behalf of the Plaintiffs in advance of the November 24, 2020 case management conference. Plaintiffs positions on the various issues are set forth below.

Case Management.

The parties have exchanged proposed case management orders ("CMOs") for significant case deadlines. Plaintiffs continue to believe the Court's intention is that the economic loss class action should be the leading edge of the parties' discovery and briefing efforts in this MDL. However, upon Defendants' insistence for a comprehensive CMO addressing all three case tracks (economic loss class action; medical monitoring class action; and personal injury), Plaintiffs'

proposed CMO reasonably proposes a staggered schedule for all three case tracks. (Exhibit 1 hereto). This includes, for example, class certification and related class expert deadlines for the economic loss and medical monitoring class actions, staggered slightly so that the medical monitoring deadlines slightly trail the economic loss deadlines. Plaintiffs' proposed schedule also address issues unique to the personal injury cases, such as general causation disclosure deadlines. The proposed personal injury deadlines also slightly trail the economic loss deadlines.

At this point, the principle philosophical disagreement between the parties appear to be whether the deadlines in all three case tracks should run exactly parallel and in lockstep with each other, or if they should be staggered. As noted above, Plaintiffs believe the economic loss deadlines should slightly precede the deadlines for the other two tracks. This makes sense for a number of reasons. First, the Court has signaled months ago that the economic loss matter will be the leading track in this MDL. Second, discovery in the economic loss track matter is substantially ahead of discovery in the other two matters. Third, fact discovery, expert discovery, and briefing in the economic loss case will be largely transferable and informative in the other two tracks, resulting in substantial efficiencies for the parties and the Court. Fourth, the Defendants' proposal actually is written as if the personal injury cases will or at least may be brought to trial before the economic loss class certification and first trial are reached, which is contrary to everything the Court has said to date. Fifth, the Defendants' proposed schedule clusters virtually all factual depositions into a tight window that will already be challenging, in order to preserve their hope that the economic loss case can be pushed to the back, which is completely unnecessary and inefficient, and flies in the face of the Court's statements to date. Sixth, the Defendants' proposal

makes it impossible to bring any segment of this litigation to a logical decision point in 2021, and in fact pushes the first potential trial of any claims likely to the summer of 2022, at the earliest.

Plaintiffs continue to advocate, consistent with prior discussions with the Court, for the litigation to be focused toward class certification and the initial economic loss trial in 2021, with the initial Defendants to be the API and finished dose manufacturers who pushed the contaminated drugs from the top of the supply chain down into the market. For example, depending on the Court's preference, that could include ZHP in its capacity as API and finished dose manufacturer, and potentially include the finished dose manufacturers who purchased the contaminated ZHP API and used it to manufacture their own finished dose products - which would then include Teva and Torrent.

30 b 6 Deposition Notices.

Plaintiffs have met and conferred separately with each of the manufacturing defendants. At the outset, Plaintiffs first spoke to ZHP and Plaintiffs were informed that they would have to meet and confer separately with each manufacturing defendant since they all were taking different positions based on their own unique circumstances. Plaintiffs expressed surprise and frustration at this declaration since the notices were essentially the same across the defendants and this was only going to multiply the time needed to negotiate and would burden the Court during the upcoming argument. However, Plaintiffs were constrained to adhere to the ground rules set by the defense and Plaintiffs therefore entered into a grueling process of negotiating separately with six different entities (ZHP and its subsidiaries constitute an entity for these purposes, but it is actually four separate notices).

Despite forcing Plaintiffs to negotiate separately with all of the manufacturers, it became clear during the evolution of the discussions that the defendants were working together behind the scenes to an extent, and this was ultimately confirmed during our discussions by a few of the defendants. Specifically, they were circulating revised versions and language, and as the discussions advanced it appeared that certain defendants acquiesced to requests by others not to confirm certain compromises that Plaintiffs thought were done. This has complicated the negotiations. In addition, some defendants seem to be clinging to disputes that are not productive – for example, Torrent will not drop boilerplate and unreasonable objections to easily understood terminology. It is likely that the Court will therefore have to wade through six separate arguments in order to finalize each of the notices since the various manufacturers have negotiated varied language on numerous points.

Addressing the substance, Plaintiffs worked hard to address the legitimate concerns raised during the discussions. The Court will see that the definitions at the start of each notice contain language confirming the scope of information to be addressed, including enhanced definitions of the foreign regulatory information and testing information to be addressed to comport with the Court's macro rulings. There are many other examples of language that was modified to accommodate various defendants' concerns. The notices Plaintiffs present attached hereto are quite reasonable, and Plaintiffs request that the Court confirm each of these are approved, and direct that no objections may be made to these finalized deposition topics – as the Court did with the Rule 34 requests. This is critical in light of the level of difficulty these defendants are

promising in the effort to depose foreign nationals in their individual capacities. Substantive objections at a later date will inject significant disputes at the last minute.

The remaining disputes are not identical across the defendants, but some repeat. For example, some defendants object to the use of the word "contamination" to describe the nitrosamine contamination. Others apparently object to the terms "root cause investigation," "SOP's" and other basic terms.

ZHP, and perhaps one or two other defendants insist that valsartan should be defined to only include the valsartan actually manufactured for sale in the United States. This of course is directly contrary to the Court's macro rulings (See Exhibits 2 and 3 hereto which are the November 25, 2019 Macro Order, and the November 20, 2019 transcript). The Court explicitly ruled that Plaintiffs can take discovery regarding what occurred in the facilities that manufactured the API and finished dose that was to be sold in the United States. In fact, paragraph 7 of the Macro Order is explicitly not limited to just the valsartan sold in the United States. The reason for the Court's ruling is obvious – the manufacturing processes, SOP's, application of cGMP's, and other relevant manufacturing information was the same across the product manufactured in the facility. Plaintiffs asked if different processes, solvents, or SOP's applied depending on where the drug was to be sold and they refused to answer or conceded that they were the same. In order to illustrate this reality, Plaintiffs have submitted examples of documents obtained in discovery demonstrating that the API and finished dose sold in the United States was plagued with the same contamination as that sold elsewhere in the world, for example in Europe and Asia. (See Exhibits 8-9 hereto). The Court will see for example a document in which it was confirmed in a document related to an

inquiry from the Korean authority that the initial process used by ZHP – the TEA process – caused NDMA contamination despite ZHP's dissemination of misinformation that it was only the later instituted process that caused this terrible problem. This shows this information was provided elsewhere in the world before the FDA was notified. (See Exhibit 5 hereto). **In fact, the revelation of the contamination came from a European arm of Novartis that discovered the contamination while analyzing ZHP API for potential sale in Europe!**

There are also a few objections to Plaintiffs' reference to both actual and potential nitrosamine contamination. Of course, one of the issues in this litigation is the extent to which untested pills were contaminated since that goes directly to causation and to damages since Plaintiffs posit that all of the pills were valueless – especially to the extent the defendants could not prove that lots or batches were not contaminated.

Plaintiffs will be prepared to address all remaining objections during the hearing.

The proposed 30 b 6 notices are presented as follows:

Exhibit 9 - Aurobindo

Exhibit 10 - Hetero

Exhibit 11 - Torrent

Exhibit 12 - Mylan

Exhibit 13 - Teva

Exhibit 14 - ZHP, Huahai, Solco, Prinston

Chinese Addendum to deposition protocol.

ZHP presented Plaintiffs with a broad addendum to the deposition protocol, seeking special treatment for ZHP's Chinese national witnesses. During the meet and confer process it became clear that much of the proposed addendum addressed theoretical issues and would in practice insert burdensome obstacles to a smooth, efficient deposition process. The following overview addresses several primary areas of dispute, and these and any other remaining disputes can be addressed during the hearing.

Chinese Privacy, State Secrecy, Civil Procedure Law and Hague Evidence Convention. The protocol proposes broad limitations on the conduct of the depositions of Chinese nationals, wherever conducted, based on a list of Chinese laws and the Hague Convention. Plaintiffs asked ZHP to explain the applicability of these laws, in order to understand whether there was a true dispute, but ZHP was unable to offer even one example of how they expected any of these laws to actually apply. Thus, Plaintiffs are being asked to accept the potential applicability of these provisions without any understanding of what they are being asked to agree to in practice. Despite ZHP's acknowledgement that these laws may have no applicability at all, and stating that they might be willing to drop their references to one or more, ZHP has left them all in as disputed issues. The bottom line is that such a sweeping provision cannot be included without a mutual understanding of how it might actually apply.

The guiding principle is that the "party relying on foreign law has the burden of showing that such law bars production." *Schindler Elevator Corp. v. Otis Elevator Co.*, 657 F. Supp. 2d 525, 532 (D.N.J. 2009). "Chinese law prohibits exporting state secrets from China without the

government's permission." *Autodesk, Inc. v. ZWCAD Software Co. Ltd.*, No. 5:14–cv–01409–EJD, 2015 WL 1928184, at *4 (N.D. Cal. Mar. 27, 2015) (Exhibit 15 hereto). More specifically:

> Article 2 of China's State Secrets Law defines state secrets as **'matters that have a vital bearing on state security and national interests and, as specified by legal procedure, are entrusted to a limited number of people for a given period of time.'**

Id. Thus, "China's state secrecy and other related laws . . . criminalize the disclosure of information that relates to Chinese national security and other potentially sensitive interests. **These laws have broad sweep and can preclude disclosure of a host of nebulously defined categories of information.**" *Munoz v. China Expert Tech., Inc.*, No. No. 07 Civ. 10531, 2011 WL 5346323, at *1 (S.D.N.Y. Nov. 7, 2001) (citing *Richmark Corp. v. Timber Falling Consultants*, 959 F.2d 1468, 1477 (9th Cir.1992)) (Exhibit 16 hereto).

Given the vague applicability of the state secret laws and the withholding party's burden to show that the laws apply, **Chinese state secret laws "are viewed with some skepticism in U.S. courts."** *Munoz*, 2011 WL 5346323, at *1; *see also* Richman, 959 F.2d at 1477 (rejecting the withholding party's invocation of Chinese state secret law); *Meggit (Orange Cty.), Inc. v. Nie Yongzhon*, No. SACV 13–0239–DOC, 2015 WL 1809354, *11 (C.D. Cal. Apr. 21, 2015) (same) (Exhibit 17 hereto); *Autodesk*, 2015 WL 1928184, at *4 (same); *Masimo Corp. v. Mindray DS USA, Inc.*, No.: SACV 12-02206, 2014 WL 12589321 (C.D. Cal. May 28, 2014) (same) (Exhibit 18 hereto).

In fact, "[t]he Supreme Court has stated that **'[i]t is well settled that [foreign "blocking"] statutes do not deprive an American court of the power to order a party subject to its jurisdiction to produce evidence even though the act of production may violate that statute.'**"

Munoz, 2011 WL 5346323, at *1 (quoting *Societe Nationale Industrielle Aerospatiale v. United States Dist. Ct., S.D. Iowa*, 482 U.S. 522, 544 n. 29 (2011)). After weighing the applicable factors under *Societe Nationale*, the Ninth Circuit has even affirmed the disclosure of information after the Chinese Secrecy Bureau ordered a party "not to disclose or provide the information and documents requested by the United States District Court for the District of Oregon," and warned that the party "shall bear any or all legal consequences should you not comply with this order." *Richman*, 959 F.2d at 1476, 1478-79.

ZHP's complete inability to offer even one example of how the state secret laws might apply, and admission that no documents have been redacted or withheld under this doctrine, renders it impossible for ZHP to establish the applicability of the Chinese laws. In *Autodesk, Inc. v. ZWCAD Software Co. Ltd.*, the Court held that:

> ZWSoft also does not show that there is a genuine risk that production of its source code and related documents under the current protective order could subject ZWSoft to liability under Chinese state secret and privacy laws. ZWSoft is correct that China has imposed "severe" penalties upon people who have violated its state secrecy or privacy laws. But once again, **ZWSoft's generalized, unsubstantiated claims about Chinese law do not establish that there is a "present danger that application of the PRC blocking statutes" could subject ZWSoft to liability if it produces its source code and related documents in the United States.**

2015 WL 1928184, at *8 (footnotes removed); *see also Masimi*, 2014 WL 12589321, at *3 (noting that the withholding party "has presented no evidence regarding the extent to which the Chinese government enforces its secrecy laws, or the likelihood that any criminal as opposed to only civil or administrative penalties will be issued, making that factor similarly less persuasive in its favor").

Here, ZHP has not explained how any Chinese state secret laws would prevent it from disclosing information subject to discovery in this case, thus it cannot meet its burden.

Despite this, aside from the complete failure by ZHP to establish the potential applicability of the Chinese laws, ZHP seeks to cement the attendance of a lawyer from China (who is not a member of any state Bar in the United States and will not be admitted pro hac vice in this case) at all Chinese nationals' depositions, to make objections on the record pursuant to these secrecy laws, including directions to witnesses not to answer questions. Again, this is set against ZHP's inability to provide an explanation as to why or how such laws could apply to a case about contaminated pharmaceutical products. Plaintiffs simply cannot agree to be bound by such a provision. The Federal Rules of Civil Procedure and Local Rules govern these depositions and any language in the Addendum to the contrary suggesting that Chinese or Hague Convention law will supplant or control the depositions, in the complete absence of any proffer or agreement as to how these laws would apply in practice, would be inappropriate.

Deposition Location and Timing – Plaintiffs have proposed that the parties work together to identify a location for the taking of the deposition that minimizes the difficulty associated with differences in time zones, or in the alternative to codify the flexibility and cooperation that will be needed to conduct the depositions with the witnesses in Hong Kong or other far flung locales. Defendants instead insist that the only location Chinese nationals will travel for deposition is Hong Kong, despite the fact that there is a 12-hour time difference between Hong Kong and the East Coast of the United States. ZHP also appears to dispute a provision that provides a partial solution to the time zone difference – breaking depositions into smaller time chunks since questioning

lawyers in the United States cannot be expected to work from 9 pm to 6 am eastern time to conduct a deposition – despite indicating during the meet and confer that this was an idea they were willing to discuss. This is the type of cooperative solution the parties should be pursuing, since breaking up the depositions into smaller chunks of time will address the most difficult aspects of these proposed depositions.

In this connection, ZHP suggests that Plaintiffs are free to apply to the Chinese Government to take a deposition in China but have failed to do so. Yet Defendants are well aware that this is not a realistic possibility, in light of the travel impossibility, and inevitable applicability of Chinese law within China, to obstruct the depositions. If ZHP thought that the conduct of full and fair depositions of witnesses inside China was a realistic possibility, ZHP would have applied for authorization to have Chinese nationals deposed in China.

Disparagement – ZHP demands that cautionary language regarding the disparagement of Chinese witnesses be placed in the Addendum. Plaintiffs object as there is already language in the deposition protocol addressing this issue.

Document Translation – ZHP suggests that all foreign language documents used in a deposition must be translated into English and provided to defense counsel in advance of a deposition and that all counsel must agree on the accuracy of the translation in advance. Plaintiffs object to this cumbersome process as unnecessary, impractical, and not required by Local Rules or the Federal Rules of Civil Procedure. Plaintiffs certainly have no intention of previewing their deposition strategy for ZHP by sharing the complete set of Chinese language documents in advance of the depositions. There is simply no need for this intrusive provision, and hope that

ZHP will reconsider its insistence on the requirements Plaintiffs have stricken (it is Plaintiffs understanding from email communications that ZHP is considering Plaintiffs' edits).

Indian Addendum.

The parties met and conferred regarding this protocol, which presents some of the same issues as the Chinese addendum. The affected manufacturers here also seek to impose unnecessary obstructions to the deposition process, while none have identified even one 30 b 6 witness. In the absence of a clear need for a foreign law or the Hague convention to be included, in response to a particular issue, these provisions should not be vaguely left in these addendums to rear their heads in unforeseen, potentially problematic and undefined ways in the future.

Teva TAR Motion.

This issue was fully briefed and most recently argued on November 11, 2020, with supplemental briefs submitted one week later. Plaintiffs stand by their position that the motion should be denied, and Teva should comply with its obligation to manually review each document for production, or produce the documents in question to Plaintiffs.

Unfortunately, Teva's most recent submission to the Court contains several misstatements that Plaintiffs must address. First, Teva argues that Plaintiffs' position is undercut by Plaintiffs' willingness to speak to Mylan regarding Mylan's similar concerns, with Teva representing that Plaintiffs' agreement to a new protocol with Mylan should be held against Plaintiffs. This argument is bewildering since Plaintiffs have reached no agreement with Mylan, and in fact no potential protocol has been exchanged. It is unclear at present whether any agreement will be reached with Mylan. Plaintiffs have simply agreed to meet and confer in good faith, as the Court

expects – and as Plaintiffs did for weeks with Teva. Aside from Teva's completely unsupported and incorrect representations to the Court, in the event Plaintiffs were to ultimately reach some accommodation with Mylan that cannot be used against Plaintiffs.

Other outright misrepresentations include Teva's representation that the provision in the protocol that was all but agreed to, providing for Teva to provide 5000 audit sample documents to Plaintiffs for review, came from the Plaintiffs. In fact, that provision was inserted by Teva, along with the methodology for the selection of those 5000 documents, with the input of Teva's consultant. Plaintiffs agreed to that provision. It is unclear why Teva chose to misrepresent the origin of that provision – seemingly suggesting that it was introduced by Plaintiffs in a discussion with the Court, which is just not true.

Finally, Teva suggests that the Plaintiffs presented the entire protocol to Teva, through the Court. That is not true. As set forth above, Teva provided a detailed protocol to Plaintiffs – this occurred on July 31, 2020. Plaintiffs then sent Teva a redline on August 2, 2020. Again, it is unclear why Teva thought that it made sense to obscure these basic facts, but the truth is that Teva presented the protocol to Plaintiffs, including the provision providing for 5000 "non-responsive" documents to be provided to Plaintiffs for validation purposes.

Finally, without going through the cases in detail, Teva once again cites to additional cases that do not aid its position, with case descriptions that significantly exaggerate their relevance to the issue before this Court. For all of these reasons, Plaintiffs ask the Court to deny Teva's application.

ZHP Production Deficiencies.

Plaintiffs have been meeting and conferring with ZHP and other Defendants regarding the production of unredacted versions of the EIRs, along with the exhibits to the EIRs. While Plaintiffs continue to meet and confer, we wanted to put this issue on the Court's radar. ZHP and other Defendants have claimed that they do not have unredacted copies of the EIRs from the FDA, and cannot determine the identity or no longer have some of the exhibits to the EIRs. To the extent Defendants do not have an unredacted copy, Plaintiffs have asked Defendants to informally go through the document with Plaintiffs in an attempt to fill in the FDA redaction gaps to come up with an agreed to version. Plaintiffs believe this to a much more efficient way to deal with the redactions than to dedicate an entire 30(b)(6) deposition to trying to fill in the gaps on the record and under oath. ZHP has refused, saying that because the FDA applied the redactions rather than ZHP, any person from ZHP opining on the nature of the redactions would only be speculating.

Wholesaler Discover Issues.

Plaintiffs have identified a number of deficiencies in all three Wholesaler Defendants' productions, ranging from overly broad redactions, to Wholesalers' newly professed claim that they do not understand the wording of multiple requests (notwithstanding the language was proposed by Defendants, and either agreed upon by both sides and/or entered by the Court), to objections to agreed-upon, Court-approved requests that were never raised with Plaintiffs or the Court during the months-long meet and confer process and oral argument.

On Friday, November 20, Wholesaler Defendants told Plaintiffs they cannot meet and confer until after Thanksgiving. Provided that Wholesaler Defendants use the ensuing time in

good faith to substantively respond in detail to Plaintiffs' identified deficiencies, Plaintiffs are amenable to this, with one exception.

That exception relates to a belated confidentiality objection to Court-approved document request nos. 5 and 7. These requests read as follows:

> 5. Produce documents sufficient to identify as exemplar the type of manufacturer-included packaging or labeling documents, shipment documents, or similar information which accompany VCDs sold by you to Retail Pharmacy Defendants or other retail pharmacies.
>
> 7. Produce documents sufficient to identify as exemplar the type of manufacturer-included packaging or labeling documents, shipment documents, or similar information which accompany VCDs sold by you to Retail Pharmacy Defendants or other retail pharmacies.

(*See* Exhibits 19-21 hereto (AmeriSource Bergen, Cardinal and McKesson written discovery responses)). All three Wholesaler Defendants objected to these heavily-negotiated, agreed-upon, Court-ordered requests on the basis that the Drug Supply Chain Security Act ("DSCSA") precludes production of the requested documents. This is the *first* time Wholesaler Defendants *ever* raised this particular issue. They did not raise in the months-long meet and confer process. They did not raise it in their lengthy written submissions to the Court. And they did not raise it during the hours-long oral argument earlier this past summer. Instead, they remained silent for months, and did not surface this particular objection until after Plaintiffs agreed to Defendants' own proposed language for these two requests, and the Court entered the requests by order dated July 9, 2020 (ECF 509).

Wholesaler Defendants' belated failure to raise any objection to producing documents in response to requests *they themselves worded* constitutes a waiver of this particular objection. They

should promptly produce the responsive documentation they previously agreed to produce, and which this Court has ordered them to produce.

PFS Issues.

The parties had a productive meet and confer on Thursday, November 20, 2020. The Parties are continuing to work to resolve many of these deficiencies and will be prepared to address any disputes as to the materiality of any remaining deficiencies at the Case Management Conference.

State Court Coordination.

The only information that Defendants have provided in response to the Court's order is the identification of Aurobindo of two cases regarding losartan. No other information has been provided pursuant to the order, preventing Plaintiffs from taking meaningful steps to seek coordination.

Thank you for your courtesies and consideration.

Respectfully,

ADAM M. SLATER